Summary of the
Implementation Committee Meeting
January 13, 1998

The Implementation Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, January 13, 1998, at 10:30 a.m. Eastern Standard Time (EST) as part of the Third NELAC Interim Meeting in Arlington, VA. The meeting was led by its chair, Dr. Carl Kircher of the Florida Department of Health, Bureau of Laboratories. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

INTRODUCTION

Dr. Kircher opened the meeting by providing an overview of the purpose of the Implementation Committee. The Implementation Committee is not charged with making changes to the NELAC standards themselves but is tasked with identifying and addressing issues surrounding the implementation of NELAC. Agenda items included:

- Approval of the December 9, 1997, Teleconference Minutes
- National Conference of State Legislators (NCSL) Survey Results
- NELAC Implementation by/for EPA Programs
- NELAC Implementation for Small Laboratories (Model Quality System)
- NELAC Cost/Benefit Analysis
- State Rulemaking Preambles, Analyte Sheet, Application Forms
- Old Business
- New Business

HANDOUTS

- National Environmental Laboratory Accreditation Conference
  Survey of State Legislators
  National Conference of State Legislators
  November 1997

- Quality Assurance Plan
  Prepared for the State of Florida
  Department of Health (DOH)
  Office of Laboratory Services
  Water Certification Program for
  Dunedin, Florida
  November 14, 1997

- Quality Assurance Plan
  City of Pembroke Pines, Public Services
  Laboratory Operations and Quality Control
  Manual for Environmental Laboratory
  November 25, 1997

- Preamble for Generic Rulemaking

- Analyte Sheet for certified laboratory testing under NELAC, Methods/Analytes

Individuals that did not receive a copy of these handouts are welcome to give Dr. Carl Kircher their card and he will provide them with copies.

APPROVAL OF THE DECEMBER 9, 1997, TELECONFERENCE MINUTES

Meeting notes from the December 9, 1997, teleconference were reviewed by committee members. Pending several minor changes, the meeting notes were approved.

NATIONAL CONFERENCE OF STATE LEGISLATORS (NCSL) SURVEY RESULTS

A survey of state legislators was conducted by the National Conference of State Legislators (NCSL). The purpose of the survey was to determine (1) the level of their knowledge and understanding of NELAC, (2) whether it was generally thought that national accreditation would be beneficial to their state, (3) the level of support they had for NELAC, and (4) the existence of state legislation relating to environmental laboratory accreditation in their states. The results of the survey have been finalized. A copy of the final report was distributed at the meeting.

In summary, NCSL received responses from 20 of the 50 States and two Territories contacted (a 40 percent response rate), and from 29 of the 170 individual legislators contacted (a 17 percent response rate). Almost all (24 yes, 1 no, and 4 not sure) of the legislators were familiar with NELAC, and two-thirds (17 respondents) indicated that NELAC would be beneficial to their states. Two-thirds indicated that they could incorporate and adopt reference materials into rulemaking (thus eliminating having to write out all the NELAC Standards in the rule). Five respondents noted that their state programs included a role for private sector partners; however, the greater percentage (17 respondents) indicated that there was no role for private sector partners. Approximately one-third (8 respondents) indicated that they were not in favor of NELAC, and three responded that they were undecided.

In opening the discussion, it was questioned whether there would be any attempt to poll or follow up with the states that did not respond to the original survey. Although the original source of funding for this project has ended and no additional resources have been allocated, the Committee indicated that additional follow up could be performed via different avenues. The first step would be to identify those states that responded to the Survey and those that did not.

Ms. Robin Santos and Ms. Barbara Hill of the Membership and Outreach Committee indicated that a number of factsheets related to NELAC had been developed for educational purposes. These factsheets could be used to educate and inform State Legislators needing additional information on NELAC. Ms. Santos volunteered to send copies of the factsheets to states that did not respond to the NCSL survey. This effort will require coordination between the Membership and Outreach and the Implementation Committees.

Another question was whether the survey had been sent to the correct people. How were people identified for receipt of the Survey? Have the critical people been identified and contacted? Specifically, the participant suggested that the Implementation Committee needs to identify the "movers and the shakers" of State Legislatures. It is these people that get bills passed. It was suggested that names of individuals were needed as well. Additional follow-up may be needed to check with each of the states to make sure that the Survey was sent to the correct people.

It was also questioned whether there was any way to identify states that did not respond to the Survey and had pending legislature on the floor. It was suggested that this information could be obtained by contacting as many of the state representatives present at this Third Interim Meeting as possible. These representatives could possibly obtain the information for us. It was also suggested that the online version of the Bureau of National Affairs (BNA) might provide an invaluable resource on legislative activities nationwide. Ms. Santos of the Membership and Outreach Committee noted that this effort was already underway. There was no need for a duplication of effort.

It was questioned whether data gaps still exist. Dr. Kircher suggested that if additional information is needed to fill in data gaps, the State of Florida has information on Out-of-State Laboratory Certifications that could be used as a supplemental source of information, since this information is currently used to determine reciprocity.

Some inaccuracies in information were noted in the Survey results. It was questioned as to whether there was any way to correct information that might be in error. This question was directed at Part II of the Survey Results, in which NCSL compiled supplemental information from state legislation regarding environmental laboratory accreditation programs and environmental laboratories in general. Some of this information may reflect older data.

NELAC IMPLEMENTATION BY/FOR EPA PROGRAMS

Dr. Kircher indicated that the Implementation Committee is continuing communications with EPA's EMMC. Ms. Jan Jablonski provided an update on EMMC activities. She indicated that national accreditation is an important issue for EMMC. There are a number of issues that have to be resolved. Currently, the EMMC is reviewing the standards and commenting on them.

Several questions regarding Regional EPA participation were raised. Regional EPA offices will not be accrediting authorities; however, there will be active participation from all program offices in the agency and in the regions. As it stands now, the role of Regional offices will be involved in assessing state certification programs, which could now include adherence to the NELAC Standards. The role of EPA Regional laboratories has not been resolved at this time.

NELAC IMPLEMENTATION FOR SMALL LABORATORIES (MODEL QUALITY SYSTEM)

Dr. Kircher provided copies of two Quality Assurance Plans that could be used as a model example for small laboratories. It was noted that quality systems for small laboratories still have to meet the performance objectives that the NELAC standards require. Meeting these objectives

is not out of reach for small laboratories; however, "thick" quality assurance plans tend to scare small laboratories and break down communications. Small laboratories comprise a large community of affected stakeholders, and they are making their concerns known. This has resulted in some states considering two (or dual) certifications programs. It is not known how many states are actually considering dual programs; however, this option may be needed to initiate NELAP. Many participants are not in favor of the dual program option.

It was noted that the "thick" quality assurance plans are comprehensive and cover many topics that may not be applicable to all laboratories. Small laboratories should be urged to look at the basic principles, decide what they actually need, and then fit themselves into the basic fundamentals of the program. A simple outline is needed to educate and assist the small laboratory community in the identification of those accreditation process and quality system elements in the NELAC Standards that are applicable to them.

Efforts should be made to reach out to the small laboratory community. Ms. Santos of the Membership and Outreach Committee pointed out that a factsheet exists that could be used to reach the small laboratory community.

Education could result in small laboratory support of NELAC. For example, it was noted that some small laboratories actually are required to maintain multiple accreditations. On-site assessments by each certifying agency would not be necessary under NELAC, and these small laboratories could realize substantial cost savings. Furthermore, accreditation under NELAC would result in inclusion in a national database, which could result in additional work to small laboratories. This type of information needs to be emphasized to the small laboratories.

Education seems to be important at this stage of implementation. Many of the concerns expressed have a lot to do with the uncertainties surrounding the unknown. Education could be used to stress that NELAC has many things in common with other programs that are already being implemented.

Finally, the Committee asked for information related to small laboratories (e.g., who they are, how the are classified, how they are characterized, any numbers that might exist). Ms. Jablonski indicated that this type of information had been sought in the past with little success. There is not a lot of available data because many of these types of laboratories do not belong to trade associations and many do not have the resources to attend NELAC meetings. Information that does exist cannot be considered very reliable. Someone suggested that one resource may be laboratory suppliers.

NELAC COST/BENEFIT ANALYSIS

Mr. David MacLean presented a "back of the envelop" cost estimate of NELAC based on personal experience. This estimate provides a starting point for future communication and facilitates identification of additional factors that may need to be considered. This estimate focuses on laboratories that have scopes of accreditation extending beyond a single state. Laboratories that serve a single state or have local clients are not included in these cost benefit analyses.

There are two costs that need to be considered: assessor fees and laboratory costs. One participant suggested that the latter costs are larger than those charged by accrediting bodies. Having a single on-site assessment will result in a reduction of the staff effort needed to participate in preparing for, hosting, and following up on the inspection process. Additional overhead laboratory staff costs could also be reduced by not having to process state certification applications in multiple formats. There should be a major cost savings for laboratories that have scopes extending beyond single states.

Although costs have been estimated, the process is not complete. Participants were asked to provide any additional information related to staff hours/effort needed to prepare for audits/participate in audits/provide follow up to audits. PT samples were not included in the cost estimate.

Although copies of the cost/benefit analysis were not available, some findings were provided. Five people-days by the laboratory assessor, 2200 - 2900 laboratory-hours associated with each inspection, four on-site days to perform assessments, and $2800 - 5500 in laboratory personnel time to respond to deficiencies could be saved. This cost estimate does not include certification fees paid to the accrediting agency.

One participant noted that a laboratory that puts in a lot of time and money into correcting deficiencies does not have a quality program in place. Costs to correct deficiencies would be the same under any program and should not be included in the NELAC cost/benefit analysis.

The question was raised as to whether anyone knew the cost of PT samples. The handout on rulemaking preambles, distributed during this meeting, includes these estimates in the Economic Impact Statement. It was not known if the PT standing committee is considering cost as one of their issues. There is no hard data to support this first draft of the cost/benefit analysis. One possible source to obtain this data could be the CNAEL report that included some cost/benefit information.

The Implementation Committee will have to spend a great deal more time on this issue. So far they have attempted to address laboratory costs and accreditation process costs. It is obvious that the final product will be a very complicated cost analysis. Since the data needed for the cost analysis is not readily available, the process is proceeding and incorporating new data as it becomes available.

The draft cost benefit analysis will be distributed for review and comment. It is important to remember that this is a draft report and that as additional data becomes available, the report will be revised. One comment suggested that a good source of data may be costs related to the accreditation of laboratories under the Safe Drinking Water Act.

It was noted that there will be tremendous training costs to get assessors qualified to audit all the new programs. All the additional training costs may drive up certification fees. A follow-up comment from the Committee mentioned that laboratory assessors in drinking water and hazardous waste programs basically have the necessary training to do the remaining programs (the system is basically in place).

STATE RULEMAKING PREAMBLE, ANALYTE SHEET, APPLICATION FORM

Dr. Kircher provided handouts that could be used as examples of what needs to be included in administrative rulemaking efforts to incorporate NELAC Standards into state certification requirements. This handout includes statements on Purpose and Effect, Facts and Circumstances, Economic Impact statements, Effects on Competition and the Open Market, and Federal Comparison statements. Some states may have additional requirements for rulemaking. The handout analyte sheet organizes certifiable test methods and analytes into the tiered Scientific discipline - EPA regulatory program - Method - Analyte scope of accreditation presented in NELAC Table 1-3. Although states do not need to adopt this format and can simplify the analyte sheet further, the presented format can render the task of determining reciprocal certification for out-of-state laboratories easier. Reviewers are asked to provide Dr. Kircher with their comments.

OLD BUSINESS

Two subcommittees were established during the last teleconference call. One committee was established to maintain communications with the EMMC and other EPA program offices; the second committee was established to continue work on the cost/benefit analysis. A motion was carried to continue work on both subcommittees.

NEW BUSINESS

There was no new business.

Attachment A

ACTION ITEMS
Implementation Committee
January 13, 1998

Item No.	Action Item	Date To Be Completed
1.	Research and provide information on existing state certification programs that were not identified in the NCSL Survey.	Annual Meeting
2.	Coordinate the mailing of factsheets with the Membership and Outreach Committee to states that failed to respond to the NCSL Survey.	Coordinate with Membership & Outreach Committee
3.	Receive comments and revise model Quality Assurance Plans for small laboratories; forward all items to Quality Systems Committee if they are addressing this issue.	Annual Meeting
4.	Develop an outline to educate and assist the small laboratory community in the critical elements of the NELAC Accreditation Process and Quality Systems needed for compliance.	Annual Meeting
5.	Research, revise, and redistribute draft cost/benefit analysis for review and comment.	Annual Meeting
6.	Receive comments and revise the rulemaking preambles and analyte sheets as per reviewer comments.	Annual Meeting

Attachment B

PARTICIPANTS
Implementation Committee
January 13, 1998

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